

REMARKS

The Status of the Claims.

Claims 1-21 and 26-35 are pending with entry of this amendment, claims 22-25 being previously cancelled. Claims 1, 7, 13, 14, 21, 29, 34 and 35 are amended herein. These amendments introduce no new matter and support is replete throughout the specification. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record. With respect to claims 1, 7, 14, 21, 29, 34 and 35, the amendments merely correct typographical errors. With respect to claims 13 support for groups R¹, R², R³ and R⁴ can be found throughout the specification. For example, see specification at page 5, line 25 and page 23, line 15. Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendments is respectfully requested.

Claim Objections.

As a preliminary matter regarding the objections to claim numbering, Applicants agree that 37 CFR § 1.126 requires the original numbering of the claims to be preserved throughout the prosecution of an application. The present application 10/070,340, was filed under 35 § 371 including original claims 1-35 of PCT application PCT/EP00/08371. Subsequently, in a Preliminary Amendment of the original claims, claims 22-25 were cancelled. Based on these facts, Applicant believes that the original numbering of claims 1-35 should be maintained, and the renumbering of the original claims to claims 1-31 should be considered improper. In the phone interview of January 18, 2005, parties agreed to retain the original numbering henceforth in communications.

Restriction.

The Examiner has restricted the claims into 10 Groups for alleged failure of the claims to form a single inventive concept under PCT Rule 13.1 (Unity of Invention). However, with regard to the restriction of certain individual Markush style claims, the restriction is

improper, as described below. Applicant proposes an alternative grouping that is proper and reduces the Examiner's search burden.

The claims were restricted in the present Office Action as follows:

Group I: claims 1-9, 18-21, and 26-27;
Group II: claims 1 and 10;
Group III: claims 1, 5, 6, 11 and 12;
Group IV: claim 13;
Group V: claims 14-17;
Group VI: claim 28;
Group VII: claim 29;
Group VIII: claims 30-33;
Group IX: claim 34; and,
Group X: claim 35.

Applicants note that their traversal applies to the separation of Groups I, II and III, and of Groups VI and VII. These Groups: 1) improperly apply rules on claim misjoinder, 2) improperly divide Markush claims by restriction, and 3) are based on incorrect characterization of the Groups.

Applicants propose the following grouping:

Group I: claims 1-12, 18, and 19 (formula I compounds, dependent on claim 1);
Group II: claim 13 (compounds based on formula IV);
Group III: claims 14-17 (compounds based on formula VII);
Group IV: claims 20 and 21 (nucleic acid determination methods);
Group V: claims 26 and 27 (methods of synthesis);
Group VI: claims 28 and 29 (detecting NAs; dependent on claims 1, 13, and 14);
Group VII: claims 30-33 (compounds based on formula VIII);
Group VIII: claim 34 (compounds based on formula IX); and,
Group IX: claim 35 (compounds based on formula X).

This grouping has only a few claims per group (only 1 independent claim/group), no single claim appears in more than one group, and this grouping certainly does *not* present an undue examination burden. This grouping does not improperly employ PCT unity of invention arguments to divide individual Markush claims. This grouping facilitates searches by providing Groups drawn to common elements. In the event that the above grouping is adopted, Applicants elect resulting Group VI (claims 28 and 29).

35 USC § 121 DOES NOT PROVIDE A BASIS TO REJECT A CLAIM FOR MISJOINDER

The Examiner had restricted certain claims based on 35 § 121 alleging lack of a single inventive concept. Claim 1 is restricted into three Groups, and claims 5 and 6 are each restricted into two Groups, in an attempt to split elements (Markush group members) of these individual claims into different Groups. This is an improper rejection for misjoinder, which is not permitted. Applicants note that all case law addressing the issue of restricting a claim away from itself, as the rejection requires here, is perfectly express that the Office **flatly lacks the authority to use 35 USC § 121 as a basis for forcing amendment of a claim.** The Courts have repeatedly stated that the divisional statute provides no basis at all for the separation of claim elements within a single claim, i.e., that the rejections for misjoinder are not permitted.

As the Courts have noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *See, In Re Weber, Soder and Boksay* 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

It has, thus, long been held that **the Office simply may not reject a particular claim on the basis that it claims independent and distinct inventions.** *See, In Re Weber, Soder and Boksay, supra.* The courts have definitively ruled that the statute authorizing restriction practice, i.e., 35 U.S.C. §121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I and In Re Haas II.* In the cases set forth above, the

courts expressly ruled that there is no statutory basis for rejecting a claim for "misjoinder" (inclusion of multiple independent inventions within a claim) despite previous attempts by the Patent Office to fashion such a rejection. For example, *In re Webber* (198 USPQ 328) sets forth the following (*see*, 331-332):

"It is apparent that §121 provides the commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner, acting under the authority of the commissioner to reject a particular claim on the same basis."

In re Haas (198 USPQ 335) interprets this as a *per se* holding, in the very next case by the court:

"In *In re Weber*... decided of even date, this court holds that § 121 does not provide a basis for rejection of a claim. To the extent that § 121 was employed as a basis for rejection, that rejection is, on the authority of *Weber*, reversed."

As the Court has also noted:

"The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it." *See, In Re Weber, Soder and Boksay* at 334.

As the Courts have repeatedly-- and pointedly-- indicated, the Office simply may not refuse to examine a claim, no matter how many inventions it embraces. Therefore, Applicant requests claims currently restricted to more than one Group be restricted to only a single Group, e.g., as in Applicant's proposed grouping.

SPECIAL CONSIDERATIONS REGARDING UNITY OF INVENTION

Markush claims 1, 5, and 6 are each restricted into two or more Groups based on an alleged lack of unity under PCT rule 13.1. Applicants note that restriction practice is not the proper administrative action to address Markush claims that lack unity of invention. If a claim presents an improper Markush (which none of the pending claims do) it may be rejected on that basis - but it may not be restricted on similar grounds. .

Because the MPEP seems at first glance to consider restriction practice of Markush style claims with respect to Unity of Invention (MPEP 803.02), a great deal of confusion has, unfortunately, become commonplace in the Office as to appropriate restriction practice when considering questions of unity of invention for Markush style claims. It is instructive to consider how this section arose in the MPEP to understand what the law is and what it is not when performing this analysis.

After the *Weber* decision, noted above, a previous version of 803.02 that purported to fashion a rejection for “misjoinder” of a Markush-style claim was actually cancelled out of the MPEP. That is, for a time, the section corresponding to MPEP 803.02 simply stated:

the subject matter formerly under this subtitle has been cancelled in view of the decisions *In Re Weber et al.* 198 USPQ 328 (CCPA 1978) and *In Re Haas* 198 USPQ 334 (CCPA 1978).

In 1980, the Courts again considered the issue of “misjoinder” in the seminal case of *In Re Harnisch* 206 USPQ2d 300 (a chemical structure case with alternate “R” groups, quite on point here), which considered whether there was a non-statutory basis for a rejection for lack of unity *that was entirely distinct from restriction practice authorized by 35 USC 121*. The Court was plainly concerned that the two issues would be confused, noting that:

It should be clear from what we have said that we adhere to our holdings in *In re Weber*, *supra* and *In Re Haas* (*Haas II*), *supra*. Nothing we have said herein is intended to change or modify them in any way; nor do we think anything said could be construed to have such an effect. The “unity of invention” concept is not to be confused with the “misjoinder” under 35 USC 121 rejection employed in *In re Weber*. In *Weber*, we dealt with the use of 35 USC 121, which deals only with restriction requirements, to support the rejection of a single claim. Here we are concerned only with the rejection of a single claim on the distinct ground that it is directed to an improper Markush group.”

The Court’s concern that the Patent Office would confuse the issues of restriction practice under 35 USC § 121 and unity of invention practice has proven to be well founded. In reinstating MPEP § 803.02, the organizers of the MPEP addressed *Harnisch* (it is the Court decision that now underlies the section), but awkwardly left the original title heading of the

cancelled text in place, seeming to suggest that the issue is really one of restriction practice. As the Court plainly and expressly made clear (*see above*), it is not.

Indeed, as the *Harnisch* court made as clear as humanly possible, the issue when considering “improper Markush” is not an issue of restriction practice at all. Instead, as the court bluntly stated above, the possibility that a Markush-style claim may lack of unity of invention, is a “*distinct ground*” of rejection. It has nothing at all to do with restriction practice. *Id.* As *Harnisch* makes entirely clear, **improper Markush is not a basis for imposing a restriction requirement at all.**

Indeed, even the Board decision that the *Harnisch* case was an appeal from had previously reversed the improper Markush rejection by the Examiner, which had been based upon 35 USC § 121 (*Haas and Weber*, discussed above, plainly required this result), and fashioned a *different* “improper Markush” rejection based upon unity of invention, an issue gleaned not from statute, but from consideration of judicial precedents (*Harnisch* at 304-305). The Court acknowledged the possibility of such a “unity of invention” style improper Markush rejection under various court precedent (but *not* under statute and, as specifically noted, ***not under 35 USC §121***), but found that a rejection was proper *only* where the members of the Markush group were “truly independent *and* distinct.” *Id.* at 306, *emphasis in the original*. The Court made quite plain that this was a high hurdle and that the Office had *not* shown a lack of unity in the relevant case, because the subject Markush members at issue were all dyes and could, accordingly, be classified together in a manner that was not “repugnant to scientific classification.” *Id.* at 305.

Accordingly, even if “unity of invention” cannot be found amongst the members of a Markush (the central allegation in the subject Restriction Requirement), 35 USC § 121 *still* does not provide a basis for *restriction* as the Office has done in the present case. As the noted above, *there is simply no such thing as a rejection for misjoinder and, accordingly, rather than restricting elements of a claim away from themselves, the only option open to the Office when attempting to make a rejection for lack of unity of invention is to attempt to make a rejection for improper Markush.* As the Courts have definitively ruled, the Office flatly lacks the statutory authority to fashion such a rejection pursuant to *restriction* practice. There is no exception to

this *per se* rule. The Courts have repeatedly noted the *per se* nature of this rule, as noted above. The Courts have never held otherwise.

In summary, it is clear that the Action confuses the concepts of restriction practice and improper Markush and, in addition, does *not* establish the requisites for either. In the case underlying MPEP 803.02, i.e., *In Re Harnisch*, the Court strongly reiterated that the divisional statute does not provide the basis for a rejection of the claims, even in the context of a Markush-style claim. *In Re Harnisch* 206 USPQ2d 300, see, e.g., headnote 6 and page 305. As clearly articulated by the *Harnisch* Court, the *only* procedure available to the Office if unity of invention is lacking is to reject the claim for improper Markush on that basis—an event that takes place not under the auspices of divisional practice articulated by 35 USC 121, or, indeed, as the *Harnisch* Court clearly articulated, *any* statutory section, but under judicially recognized precedent with respect to “unity of invention.” The hurdle in making such a unity rejection is high, i.e., that the members of the Markush group must be “truly independent *and* distinct” (emphasis in the original) or, as the Court stated another way “repugnant to scientific classification.” This cannot be established in the present case.

Claim, 1, 5, and 6 are to a nucleic acid binding compound comprising a backbone with at least one Formula I heterocyclic group capable of base pairing to natural nucleobases. The formula of the claim includes substituent groups independently selected from Markush style lists of alternate groups. Rejection of the claim for an alleged improper Markush grouping would require the Examiner to state facts showing that grouping of particular Markush elements is repugnant to scientific classification. (Again, such an allegation can never be the basis for restriction of the claim.) However, assuming such an allegation were presented, Applicants believe the rejection would fail because, e.g., the members of each Markush group work at the same location on the same formula structure, and work to provide compounds of the invention with a common function of nucleic acid binding. Such Markush groupings can not reasonably be considered repugnant to scientific classification. Thus, there is no basis in the subject case for making an improper Markush rejection, any more than there is a basis for restriction of individual components of a claim away from themselves.

Careful review of MPEP 803.02, third paragraph, makes it clear that a Markush-type claim can include independent and distinct inventions. When this is alleged, the Examiner may require a **provisional election of species** prior to examination in the merits. However, MPEP 803.02 is not a basis for restriction of Markush claims into multiple groups. The Examiner has agreed to this interpretation and suggested Applicants provide elected species for any elected restriction group.

BRIEF DISCUSSION OF THE CLAIMS AND THE RESTRICTION REQUIREMENT

Applicants have discovered, *inter alia*, that certain nucleic acid binding compounds comprising a backbone structure and having certain modified nucleobases are useful in many nucleic acid binding technologies. Claims to these technologies would be properly restricted according to the Applicants proposed grouping and not according to the current restriction grouping.

The Action incorrectly asserts that restriction is proper because claims of the Groups they lack the same or corresponding technical features. However, as discussed below, members of the proposed Groups do have common utilities and share substantial structure features. For example, with regard to claims 1-12, 18, and 19, of proposed Group I compounds, there is a common dependency on claim 1, including a common basis in structural formula I, and all the compounds are useful as nucleic acid binding compounds. With regard to claims 28 and 29, of proposed Group VI methods of detecting nucleic acids, there is a common dependency on claims 1, 13, and 14 including common features of structural formulas I, IV, VI, and VII. Searching the proposed Group I and Group VI would not be unduly burdensome because the required searches involved for claims within the groups would be essentially the same.

Claims 1-12, 18, and 19 should be incorporated into a single Group.

Applicants note that restriction between Groups I, II and III is improper because the claims in the different Groups are all dependent on claim 1. Groups II and III in the Examiner's grouping include only claims dependent on claim 1 of Group I, simply requiring the use of alternate backbones or "R" groups in the structures. As a logical matter, any search that is properly conducted, e.g., for claims 2, 3, 4, or 5 will encompass the subject matter of the other claims, and vice versa. Searches of the dependent claims will be in the same classification, so

the burden is minimal. The number of claims in Applicant's proposed Group I does not exceed an unreasonable number, so restriction to three Groups should not be required.

Applicant notes that restriction between Groups I, II and III is improper because they include common claims. For example, it is improper (as described above) to have claim 1 as a member of each of Group I, II, and III. It is improper to have claims 5 and 6 as members of both Group I and Group III.

With regard to Examiner's Group I, the stated logic for restriction is incorrect. Group I is not drawn to nucleic acid binding compounds comprising a backbone of formula II. Group I comprises claims with a common nucleobase of formula I; only dependent claim 7 includes a formula II backbone element. As stated above, based on the common formula I nucleobase element, Group I, II and III should be combined.

With regard to Examiner's Group II, the stated logic for restriction is incorrect. Group II is not drawn to nucleic acid binding compounds comprising a backbone of formula III. Claim 1 does not include the element of a formula III backbone. However, claim 10 is dependent on claim 1 and has the structural formula I nucleobase in common with claim 1 (and other claims of Applicant's proposed Group I).

With regard to Examiner's Group III, the stated logic for restriction is incorrect. Group III is not drawn to nucleic acid binding compounds comprising a backbone of formula V. Claims 1, 5, and 6 do not include the element of a formula V backbone. Although claim 11, and its dependent claim 12, do include a formula V backbone element, they are ultimately dependent on claim 1 including the formula I structure common to Applicant's proposed group I.

Applicant's proposed Group I does not include claims 26 and 27 to methods of synthesis, dependent on claims 1, 13 (including formula VI) and 14 (including formula VII). Claims 22 and 23 have been moved to Applicant's proposed Group V. This makes Applicant's Group I more reasonable and convenient to search than the Examiner's current Group I.

Applicant respectfully requests grouping of claims 1-12, 18, and 19 into a common restriction Group.

Claims 24 and 25 should be incorporated into a single Group.

Applicants have proposed merging current restriction Groups VI (claim 28) and VII (claim 29) into a single Group. In the Action, the Examiner states that each of Group VI and VII are "drawn to a method for the determination of the presence or absence of nucleic acid", in apparent acknowledgement that the claims are highly similar. In addition, the bulk of the search required for these claims involves their common dependency on claims 1, 13, and 14. Searching the technology of claims 28 and 29 in a common Group would be efficient and require little additional effort over searching either claim alone. Applicant requests claims 28 and 29 be combined into a single restriction group.

ELECTION OF SPECIES

In the phone interview of January 18, 2005, the Examiner requested that a Response to the Office Action of November 4, 2004, include election of Markush species associated with the elected restriction group. Applicants have elected Examiners Group VII (claim 29); or alternately, election of Applicants' proposed Group VI (claims 28 and 29). In either case, Markush species exist in claims 1, 13, and 14, from which the elected claims are dependent.

With regard to claim 1, Applicants elect the following species, for prosecution on the merits:

W is	N;
Z is	N;
X is	N;
Y is	CR ⁴ ;
R ¹ is	NH ₂ ; and,
R ⁴ is	H.

With regard to claim 13, Applicants elect the following species for prosecution on the merits:

A is	O;
R ¹⁴ is	H;
R ¹⁵ is	H;

R ¹⁶ is	H;
M is	Oxy;
M' is	Oxy;
W is	N;
Z is	N;
X is	N;
Y is	CR ⁴ ;
R ¹ is	NH ₂ ; and,
R ⁴ is	H.

With regard to claim 14, Applicants elect the following species for prosecution on the merits:

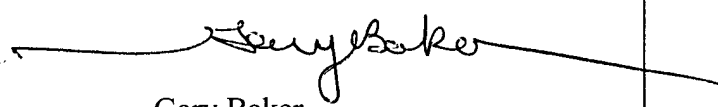
A is	O;
R ¹⁴ is	H;
R ³¹ is	a protecting group;
R ³² is	(C ₁ -C ₁₀)-alkyl;
R ¹⁷ is	(C ₁ -C ₁₀)-alkyl;
R ¹⁸ is	(C ₁ -C ₆)-alkoxy substituted one or more times by a cyano group;
M is	Oxy;
M' is	Oxy;
W is	N;
Z is	N;
X is	N;
Y is	CR ⁴ ;
R ¹ is	NH ₂ ; and,
R ⁴ is	H.

CONCLUSION

Applicants believe the foregoing is fully responsive to the Office Action. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 510-769-3510.

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Respectfully submitted,


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Attachments:

- 1) A receipt indication postcard.
- 2) A petition to extend the period of response for 3 months;
- 3) A transmittal sheet;
- 4) A fee transmittal sheet; and,
- 5) A receipt indication postcard.